UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,494	08/17/2001	Trang T. Le	C-3320/1/US	5208

26648 7590 05/17/2005

PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
POST OFFICE BOX 1027
ST. LOUIS, MO 63006

EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,494	LE ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,10-13,18-25,28-41,46-48,50-53,62-83,86-91,93 and 95-101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,10-13,16-25,28-41,46-48,50-53,62-83,86-91,93 and 95-101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *05/10/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination, Amendment, and Request for Extension of Time filed 02/28/05.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/28/05 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-91, 93 and 95-101 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the

limitation "means for pre-wetting the material to be granulated, and means for increasing air flow along the periphery of the granulation bowl" in claim 1, as well as, the limitation "a means for inhibiting agglomeration of the drug" in claim 99. Further clarification is suggested.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-91, 93 and 95-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected in the use of the phrase "means for pre-wetting the material to be granulated, and means for increasing air flow along the periphery of the granulation bowl". Nowhere in applicant's specification defines the "means" for pre-wetting or for increasing air flow.

Claim 99 is rejected in the use of the phrase "means selected from the group consisting of addition of a wetting agent, means for pre-wetting the material to be granulated, and means for increasing air flow along the periphery of the granulation bowl". Nowhere in applicant's specification defines the "means" for pre-wetting or for increasing air flow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 10-13, 18-21, 23-25, 28-41, 46-48, 51-53, 62-83, 86-91, 93 and 96-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, in view of Talley et al. US 5,760,068.

Mizumoto teaches quick-dissolved compressed tablet comprising saccharide having high moldability and saccharide having low moldability (columns 6-7), drug, and additive agents (columns 13-19, claims 1-6). The drug used is in an amount of about 50%, and is not limited but include both analgesic and anti-inflammatory drugs (column 7). The method for preparing the tablet is disclosed in columns 12-13. The composition further comprises lubricant, *e.g.*, magnesium stearate, sucrose fatty acid ester, polyethylene glycol, or talc (column 13, lines 52-55). The hardness, strength, and disintegration time is disclosed in column 11.

Mizumoto does not specifically teach the claimed active agent to be a COX-2 inhibitor. However, COX-2 inhibitor is a well-known analgesic agent, particularly, anti-inflammatory, which can be used in conjunction with other analgesic agents.

Talley '068 teaches COX-2 such as celecoxib is a known anti-inflammatory agent (column 4, lines 30-56; column 19, lines 40-45; and example 2). Thus it would have been obvious for one of ordinary skill in the art to prepare the quick-dissolved

formulation of Mizumoto using the COX-2 inhibitor, such as celecoxib in view of the teachings of Talley, because the references teach the advantageous results in the use of a well-known anti-inflammatory agent.

The examiner notes that the cited references are silent as to the amounts of glidant, and wetting agent being claimed in claims 18-20 and 23-25. However, it is the position of the examiner that no criticality is seen in the particular amounts since the prior art in using the claimed ingredients, obtains the same results desired by the applicant, *e.g.*, tablet comprising analgesic agent having disintegration rate of 1-40 seconds. See also *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Claims 1, 22, 50 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. and Talley et al., in view of Jain et al. US 6,316,029.

Mizumoto and Talley are relied upon for the reason stated above. The references do not teach the specific glidant, and wetting agent.

Jain teaches process for preparing rapidly disintegrating solid oral dosage form comprising sodium lauryl sulfate and silicon dioxide (columns 8-9). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to use the sodium lauryl sulfate and silicon dioxide in view of the teaching of Jain to prepare the quick-dissolved formulation of Mizumoto since sodium lauryl sulfate and silicon dioxide are well known tabletting aids. The expected result would be compressed tablet having good hardness and dissolved quickly upon contact with fluid.

Response to Arguments

Applicant's arguments filed 02/28/05 have been fully considered but they are not persuasive.

Claims 1-3, 10-13, 18-21, 23-25, 28-41, 46-48, 51-53, 62-83, 86-93 and 96-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, in view of Talley et al. US 5,760,068.

Applicant argues that nowhere do Mizumoto or Talley, taken alone or together, describe or suggest preparing compositions according to the process of claim 1 that includes a step selected from the group consisting of addition of a wetting agent, means for pre-wetting the material to be granulated, and means for increasing air flow along the periphery of the granulation bowl, wherein the wetting agent is as defined in claim 1. Contrary to the applicant's argument, first, the wetting agent is broadly defined in claim 1 as any hydrophilic polymers, any clays, or certain surfactants; second, the step of inhibiting agglomeration can be as broad as adding a wetting agent. Mizumoto teaches adding additive agents, such as corn starch, potato starch, carboxymethylcellulose calcium, powdered acacia, gelatin, pullulan, sodium bicarbonate, magnesium stearate, sucrose fatty acid ester, polyethylene glycol, talc, and mixture of two or more (column 13, lines 32-66). Accordingly, the group of additives being taught by Mizumoto falls within the claimed wetting agent.

Claims 1, 22, 50 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. and Talley et al., in view of Jain et al. US 6,316,029.

Applicant argues that there is no reason to combine Mizumoto, Talley and Jain because nothing in Jain suggests the need for formulating their poorly soluble drug and surface stabilizer with the saccharide having low moldability and the saccharide having high moldability required by Mizumoto. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Mizumoto teaches the use of tableting additives. Jain is relied upon solely for the teaching of tableting additive such as surfactant, including sodium lauryl sulfate. Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argues that Mizumoto demonstrates that his compositions may successfully be prepared without the addition of, for example, surfactants such as sodium lauryl sulfate and silicon dioxide described in Jain. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is

noted that the features upon which applicant relies (i.e., sodium lauryl sulfate and silicon dioxide) are not recited in the independent claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). However, applicant's attention is called to the additives being used by Mizumoto such lubricant including magnesium stearate, or polyethylene glycol. To place the application in condition for allowance, it was suggested to incorporate both, sodium lauryl sulfate and silicon dioxide into all independent claims. No agreement was reached.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Tran
Patent Examiner
AU 1615